

Novoseven RT (coagulation factor VIIa [recombinant])
SevenFact (factor VIIa [recombinant])
 Effective 03/01/2021

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Recombinant factor VIIa, a vitamin K-dependent glycoprotein, promotes hemostasis by activating the extrinsic pathway of the coagulation cascade.

NovoSeven is approved for:

1. Congenital factor VII deficiency
2. Hemophilia A with Inhibitors
3. Hemophilia B with Inhibitors
4. Glanzmann's Thrombasthenia
5. Acquired Hemophilia
6. Acquired von Willebrand Syndrome
7. Inhibitors to Factor XI

SevenFact is approved for:

1. Hemophilia A with Inhibitors
2. Hemophilia B with Inhibitors

Coverage Guidelines

Congenital Factor VII Deficiency

Authorization for NovoSeven may be granted for treatment of congenital factor VII deficiency.

Hemophilia A with Inhibitors

Authorization may be granted for NovoSeven or SevenFact for the treatment of hemophilia A with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer ≥ 5 BU.

Hemophilia B with Inhibitors

Authorization may be granted for NovoSeven or SevenFact for the treatment of hemophilia B with inhibitors (see Appendix) when the inhibitor titer is ≥ 5 Bethesda units per milliliter (BU/mL) or the member has a history of an inhibitor titer ≥ 5 BU.

Glanzmann's Thrombasthenia

Authorization may be granted for NovoSeven for the treatment of Glanzmann's thrombasthenia.

Acquired Hemophilia

Authorization may be granted for NovoSeven for the treatment of acquired hemophilia.

Acquired von Willebrand Syndrome

Authorization may be granted for NovoSeven for the treatment of acquired von Willebrand syndrome when other therapies failed to control the member's condition (e.g., desmopressin or factor VIII/von Willebrand factor).

Inhibitors to Factor XI

Authorization may be granted for NovoSeven for the treatment of inhibitors to factor XI.

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 36 months

Appendix

Appendix: Inhibitors - Bethesda Units (BU)

The presence of inhibitors is confirmed by a specific blood test called the Bethesda inhibitor assay.

- High-titer inhibitors:
 - > 5 BU/mL
 - Inhibitors act strongly and quickly neutralize factor
- Low-titer inhibitors:
 - < 5 BU/mL
 - Inhibitors act weakly and slowly neutralize factor

References

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4. Federici AB, Budde U, Castaman G, Rand JH, Tiede A. Current diagnostic and therapeutic approaches to patients with acquired von Willebrand syndrome: a 2013 update. *Semin Thromb Hemost.* 2013;39(2):191-201.
5. O’Connell NM. Factor XI deficiency – from molecular genetics to clinical management. *Blood Coagul Fibrinolysis.* 2003;14(Suppl 1):S59-S64.
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7. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia.* 2013;19(1):e1-e47.
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11. Rajpurkar M, Chitlur M, Recht M, Cooper DL. Use of recombinant activated factor VII in patients with Glanzmann’s thrombasthenia: a review of the literature. *Haemophilia.* 2014;20(4):464-471.
12. Duga S, Salomon O. Congenital factor XI deficiency: an update. *Semin Thromb Hemost.* 2013;39(6):621-631.
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Review History

01/23/2020 – Transitioned from SGM to Custom Criteria; added SevenFact to criteria. Effective 03/01/21.

